

RULE

Department of Health and Hospitals Office of the Secretary

Informed Consent—Urology (LAC 48:I.2449)

As authorized by R.S. 40:1299.40(E), as enacted by Act 1093 of 1990 and later amended by Act 962 of 1991, and Act 633 of 1993, the Department of Health and Hospitals, Office of the Secretary, in consultation with the Louisiana Medical Disclosure Panel, hereby enacts rules which require which risks must be disclosed under the Doctrine of Informed Consent to patients undergoing medical treatments or procedures and the Consent Form to be signed by the patient and physician before undergoing any such treatment or procedure.

Title 48

PUBLIC HEALTH

Part I. General Administration

Chapter 23. Informed Consent

§2449. Urology

NOTE: Itemization of the procedures and risks under a particular specialty does not preclude other qualified practitioners from using those risks identified for that particular procedure.

- A. Nephrectomy (complete or partial removal of kidney)
 - 1. bleeding;
 - 2. infection;
 - 3. injury to adjacent organs such as lung, spleen, liver, bowel, adrenal gland (if not removed);
 - 4. incomplete removal of tumor, if present.
- B. Extracorporeal Shock Wave Lithotripsy (using shock waves to break up kidney or ureteral stones)
 - 1. bleeding in or around kidney;
 - 2. obstruction of kidney by stone particles;
 - 3. failure to completely fragment stone requiring repeat treatment or other form of treatment;
 - 4. high blood pressure (transient or permanent);
 - 5. loss of kidney.
- C. Cystectomy with Urinary Diversion (removal of bladder with use of bowel to drain urine)
 - 1. bleeding requiring blood transfusion;
 - 2. infection;
 - 3. injury to adjacent organs (bowel, blood vessels, nerves, etc.);
 - 4. impotence (loss of erection functions);
 - 5. ostomy problems (scarring, infection) which might necessitate re-operation.
- D. Transurethral Prostatectomy (use of lighted scope and cautery to internally remove portion of prostate causing blockage)
 - 1. bleeding requiring transfusion or re-operation;
 - 2. infection;
 - 3. injury to bladder or urethra or rectum;
 - 4. impotence;
 - 5. retrograde ejaculation ("dry ejaculation"- backward flow of ejaculate fluid into bladder) producing infertility;
 - 6. bladder neck contracture-formation of scar tissue causing bladder blockage requiring repeat surgery or treatment;
 - 7. incontinence (urinary leakage).
- E. Radical Prostatectomy (total removal of prostate gland)
 - 1. bleeding;
 - 2. infection;
 - 3. injury to adjacent organs (blood vessels, bowel, nerves);
 - 4. blockage of ureters (kidney drainage tubes);
 - 5. erectile dysfunction (impotence, i.e., loss of erection/ejaculation);
 - 6. incontinence (urinary leakage).
- F. Bladder Suspension (MMR, Purerya - Procedure, Cystocele repair, etc.)
 - 1. bleeding;
 - 2. infection;
 - 3. blockage of ureters (kidney drainage tubes);
 - 4. persistent leakage;
 - 5. urinary fistula (abnormal hole in connection between bladder, vagina, etc.);

6. inability to void.
- G. Vasectomy
1. bleeding;
 2. infection;
 3. testicular swelling or pain/possible loss of testicular function;
 4. spermatic granuloma (nodule in cord at site of surgery);
 5. recanalization ("re-connection" of vas tube resulting in becoming fertile again).
- H. Penile Implant
1. bleeding;
 2. infection (with possible loss of implant);
 3. penile pain or numbness;
 4. injury to bladder or urethra;
 5. problems with implantable prosthetic.
- I. Orchiectomy (removal of testicle)
1. bleeding;
 2. infection;
 3. loss of hormone (testosterone) resulting in erection problems, decreased energy, etc.;
 4. loss of fertility (ability to have children).
- J. Varicocele Repair (ligation/tying of spermatic veins)
1. bleeding;
 2. infection;
 3. injury to spermatic cord (vas deferens), testicular artery, nerves;
 4. testicular swelling or pain;
 5. possible loss of testicle due to blood vessel injury or infection (rare).
- K. Transurethral Resection of Bladder Tumor
1. bleeding;
 2. infection;
 3. perforation of bladder;
 4. obstruction of ureter (kidney drainage tube).
- L. Circumcision (removal of penile foreskin)
1. ulceration and scarring of urine hole at tip of penis (meatal stenosis);
 2. bleeding;
 3. infection (minor or serious);
 4. removal of too much or too little skin;
 5. skin bridge;
 6. fistula (abnormal hole in urine tube);
 7. buried penis.
- M. Hernia/Hydrocele (removal of fluid filled sac)
1. injury to sperm duct (vas deferens);
 2. injury to blood vessels of testis;
 3. atrophy (shriveling) of the testicle with loss of function;
 4. reaccumulation of hernia or fluid in scrotum.
- N. Hypospadias Repair (Correction of Penile Curvature/Urethroplasty) (Construction/reconstruction of drainage tube from bladder)
1. leakage of urine at surgical site;
 2. stricture formation;
 3. residual curvature of penis;
 4. disfiguring scars;
 5. injury to glans (head of penis);
 6. additional operations.
- O. Ureteral Reimplantation (Reinserting ureter, tube between kidney and bladder, into the bladder)
1. leakage of urine at surgical site;
 2. obstruction to urine flow;
 3. damage to or loss of ureter (kidney drainage tube);
 4. backward flow of urine from bladder into ureter (kidney drainage tube);
 5. damage to other adjacent organs;
 6. damage to kidney.
- P. Pyeloplasty (pyeloureteroplasty - reconstruction of kidney drainage system)
1. obstruction of urinary flow;
 2. leakage of urine at surgical site;
 3. injury to or loss of kidney;
 4. damage to adjacent organs;

5. decrease in kidney function- temporary/ permanent;
6. infection with resultant failure of surgery and/or loss of kidney function.

Q. Orchiopexy (surgically placing an undescended testicle into the scrotum)

1. atrophy (shriveling) of the testicle with loss of function;
2. removal of the testicle;
3. injury to the vas deferens;
4. inability to completely bring the testicle into the scrotum in a single surgical procedure;
5. recurrent hernia formation;
6. infraction with possible loss of testicle.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1299.40(E) et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Louisiana Medical Disclosure Panel, LR 22:31 (January 1996).

Bobby P. Jindal
Secretary

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